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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/301,842 04/29/99 FERNANDES

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EXAMINER

QM32/0927

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7000 CENTRAL AVENUE NE
MINNEAPOLIS MN 55432

LAM, A

ART UNIT

PAPER NUMBER

3763

DATE MAILED:

09/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/301,842

Applicant(s)

FERNANDES ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-75 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites the limitation "the flow occluder" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 37 recites the limitation "constituent material of the insert" in lines 4-5 of claim 37. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 12, 14, 15-17, 18-22, 24-26, 28-30, 34, 35-37, 38, 41, 42, 44-49, 52, 53, 55-57, 59, 60-66, 69-71 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Tweden et al., 5,895,419. Tweden discloses an implantable medical

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device at 22, a fabric overlayer at 24. It is implied that the device may be coated with therapeutic agents, see column 4, lines 21-22.

With regard to claims 2-5, 22, 30, 37, 42, 47, 63, the constituent material comprising a polymer is disclosed at column 3, line 36, and in particular, silicone, column 3, line 38.

With regard to claims 6-8, 53, 57, 62, 66 the polymer fiber being polyethylene is disclosed at column 3, line 37, and the polymer fiber being polyester or polyethylene terephthalate is disclosed at column 5, lines 34-35.

With regard to claims 12, 34, 44, 69, antimicrobial agent is disclosed at column 4, line 22.

With regard to claims 14, 15, 17, the therapeutic agent being coated on or compounded into the body portion of the device is disclosed at column 4, lines 32-39.

With regard to claim 21, a sewing ring is disclosed at 66.

With regard to claims 25, 28, 35, 36, a heart valve prosthesis is disclosed at 10, and it is disclosed that the heart valve may be bioprosthetic or mechanical, see column 2, lines 3-6, and lines 30-35.

With regard to claims 26, 38, 48, 49, 64, 65 the body portion comprising a metal, titanium in particular, is disclosed at column 3, line 40.

With regard to claim 35, an occluder is disclosed at column 2, line 32.

With regard to claim 37, a flow occluder disk is disclosed at 14.

With regard to claim 41, an annuloplasty ring is disclosed at 22.

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With regard to claim 45, a sewing ring is disclosed at 66.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11, 23, 27, 32, 33, 39, 40, 43, 50, 51, 54, 58, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tweden et al., 5,895,419, in view of Fearnot et al., 5,609,629. Tweden discloses the invention substantially as claimed, see above regarding claim 1. However, Tweden does not disclose the therapeutic agent being an anti-inflammatory agent, or in particular, dexamethasone.

Fearnot teaches that a layer of dexamethasone coated on an implantable medical device for implantation into, for example, the vascular system, see column 4, line 33. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to apply a layer of dexamethasone onto an implantable medical device, such as the Tweden heart valve, as a known therapeutic agent for use with a medical device for implantation into the vascular system.

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Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tweden et al., 5,895,419, in view of Chanda et al., 5,645,587. Tweden discloses the invention substantially as claimed, see above with regard to claim 1. However, Tweden does not disclose the antimicrobial agent being gentamicin or rifampicin.

Chanda teaches that heparin after neutralization with gentamicin is essential in prevention of calcification in tissue grafts, which is the main cause of failure of bioprosthetic heart valves, see column 3, lines 45-47, and lines 61-62. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a gentamicin in combination with heparin on the Tweden heart valve in order to prevent calcification.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tweden et al., 5,895,419, in view of Myers, 5,716,397. Tweden discloses the invention substantially as claimed, see above with regard to claim 1. However, Tweden does not disclose a polymer insert comprising radiopaque flexible silicone rubber.

Myers discloses an annuloplasty ring consisting of a soft core of silicone rubber impregnated with radiopaque salt. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide radiopaque silicone rubber in the Tweden polymer insert, as a known material used in forming an annuloplasty ring.

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Claims 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tweden et al., 5,895,419. Tweden discloses the invention substantially as claimed, see above with respect to claim 1, except that Tweden does not disclose an implantable infusion pump with a polyester pouch surrounding the pump, and a constituent material in intimate contact with an anti-inflammatory agent.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that a polyester outer layer surrounding a metal or polymer frame can be used in an implantable pump, as known materials used in implantable devices, such as a heart valve as disclosed by Tweden, see column 3, lines 30-36.

Moreover, Fearnot teaches that a layer of dexamethasone coated on an implantable medical device for implantation, see column 4, line 33. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to apply a layer of dexamethasone onto an implantable medical device, as a known therapeutic agent for use with a medical device for implantation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seidel Richard can be reached on (703)305-3009. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L. 
September 24, 2000


Sharon Kennedy
Primary Examiner